



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Avantis Medical System, Inc.
Mr. Scott Rutherford
Director of Regulatory and Quality Affairs
263 Santa Ana Ct.
Sunnyvale, CA 94085

JUL 27 2015

Re: K070330
Trade/Device Name: Avantis Medical Systems, Inc. Third Eye™ Retroscope™
Auxiliary Endoscopy System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDF, FDS, FCQ and KNW
Dated (Date on orig SE ltr): April 5, 2007
Received (Date on orig SE ltr): April 6, 2007

Dear Mr. Rutherford,

This letter corrects our substantially equivalent letter of April 24, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070330

Device Name: Avantis Medical Systems, Inc. Third Eye Retroscope Auxiliary Endoscopy System

Indications for Use:

The Avantis Medical Systems, Inc. Third Eye Retroscope Auxiliary Endoscopy System is intended for use in the instrument channel of a standard colonoscope to provide retrograde illumination and visualization of the colon for diagnostic purposes.

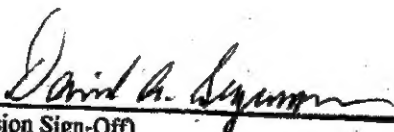
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070330

Avantis Medical Systems
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Tel: (408) 733-1901, FAX: (408) 733-1847

APR 24 2007

Section 1: 510(k) Summary

This section is prepared in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Summary Date: February 2nd, 2007

Owners Name: Avantis Medical Systems, Inc
Address: 263 Santa Ana Court
Sunnyvale, CA 94085
Phone: 408-733-1901
Fax: 408-733-1784

Contact Person: Scott Rutherford
Phone: 408-733-1901 x227

Device Information:

Classification: Class II
Classification Name: Colonoscope, FDF / 21 CFR 876.1500
Trade Name: Third EyeTM RetroscopeTM System
Common Name: Endoscope

Identification of Predicate Devices:

The Avantis Third Eye Retroscope is substantially equivalent in intended use and operation to a combination of predicate devices:

K032177	Olympus Evis CF-140L/I/S Colonovideoscope (see note 1)
K853585	Olympus Evis Video System Center CV-100 (see note 2)
K924106	US Endoscopy, Disposable Biopsy Forceps, Colonoscope, and fenestrated Oval cup with Spike and Sheath, part number 00711205
K984358	Olympus Distal Attachment

Note 1 – No direct 510K was found for the CF-140L/I/S under FDF classification code. This product is currently available in the resale market. K032177 lists Olympus Colonoscope XCF-Q140ML/I in intended use which relates to the predicate CF-140L/I/S.

Note 2 – No direct 510 was found for the Evis Video Center CV-100. This product is currently available in the resale market under Olympus CV-100 Evis Video System Center. K853585 describes a full video system center for multiple modalities. The Third Eye Retroscope Video Processor indications are applicable to the colonoscopy section of the predicate video system center.

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Device Description Summary:

The Third Eye Retroscope Auxiliary Endoscopy System is designed as an auxiliary device for use during a colonoscopy procedure.

After a colonoscope has been advanced to the cecum, the Third Eye Retroscope auxiliary Endoscopy device is inserted **through the instrument channel of the colonoscope**. As the auxiliary device emerges from the distal tip of the instrument channel of the colonoscope, the auxiliary device automatically bends 180 degrees to form a "J" shape. The device then provides a continuous retrograde image of the colon throughout the process of withdrawal of the colonoscope.

The Third Eye Retroscope is deployed through the instrument channel of a colonoscope in what is commonly referred to as a mother-daughter configuration. As a result, only approximately 4 cm of the distal tip of the device protrudes from the distal end of the colonoscope's instrument channel except for a few seconds during insertion and removal, when up to 9 cm of the distal tip extends beyond the end of the colonoscope. Any contact of the device with the colonic mucosa is transitory.

The system consists of both disposable portions, and facility equipment.

The disposable portions include the Third Eye Retroscope and Cap. The Third Eye Retroscope is an endoscope that consists of a distal section, flexible insertion tube and proximal section. The distal section houses an imaging sensor, light source and related circuitry. The flexible insertion tube consists of a standard braided catheter with electrical wires located inside the lumen. These wires carry signals from the distal region to the proximal region. The proximal section includes a torquing knob, flexible wire extension region, and electrical connector. The Third Eye Cap with polarizing filter is placed on the distal end of the colonoscope.

The facility equipment portions of the device include the Third Eye Retroscope Video Processor and accessories. The video processor is a piece of electrical equipment that acts as an interface box for the Third Eye Retroscope, the video output signals, and user input controls. The output video signals from the video processor are displayed on a monitor for viewing by the physician. Application software that runs on the video processor allows the user to adjust various picture settings of the Third Eye Retroscope image and adjust the light intensity of the Retroscope. Additionally, the software facilitates the capture of still images, the export of these still images, and allows a user to save system settings under a profile name.

Intended Use:

The Third Eye Retroscope Auxiliary Endoscopy System is intended for use in the instrument channel of a standard colonoscope to provide retrograde illumination and visualization of the colon for diagnostic purposes.

Comparison to Predicate Device

The Third Eye Retroscope Auxiliary Endoscopy System is intended to be used as an auxiliary imaging system for colonoscopes. The Third Eye Retroscope Auxiliary Endoscopy System is similar to the combination of listed predicate devices in indication for use, sterilization method, physician operation, materials, and safety.

The Third Eye Retroscope is inserted into the instrument channel of a colonoscope in a similar manner to the predicate biopsy forceps. Once in place, the Third Eye Retroscope is designed to provide images of the colon in a similar manner as the predicate colonoscope. However, the Third Eye Retroscope image provides a retrograde view of the colon whereas the colonoscope provides a forward view. The Third Eye Retroscope is controlled by the Third Eye Video Processor in a similar manner as a colonoscope is controlled by the predicate Video System Center.

Based on the intended use, descriptive information, and performance evaluation provide in this premarket notification, including in vitro bench testing, the Avantis Medical Systems, Inc. Third Eye Retroscope Auxiliary Endoscopy System has been shown to be substantially equivalent to the currently marketed predicate devices.

The table below lists a summary of the predicate devices, and key similarities and differences:

Table 1-1 – Comparison of Third Eye Retroscope Auxiliary Endoscopy System and Predicate Devices

Avantis Product	Parameter	Predicate Devices			
		Olympus Evis CF-140L Colono-videoscope	Olympus Evis Video System Center CV-100	US Endoscopy, Disposable Biopsy Forceps 00711205	Olympus Distal Attachment
	510K Number	K032177	K853585	K924106	K984358
Third Eye Retroscope	Similarities:	Indication for Use, Imaging Performance		Delivery method into colon, Sterility, Single Patient Use Size & shape	
	Differences from predicate:	Not steerable, Less complex, Auxiliary device		Not surgical Includes electronics	
Third Eye Cap	Similarities:				Attachment to colonoscope, Single Use, Size & Shape
	Differences from predicate:				Not Surgical
Third Eye Video Processor	Similarities:		Indication for Use, Size & Shape, performance		
	Differences from predicate:		No Light Source, Less Complex, Split Screen capability		

Summary

Based on the intended use, descriptive information, and performance evaluation provided in this premarket notification, including in vitro bench testing, the Avantis Medical Systems, Inc. Third Eye Retroscope Auxiliary Endoscopy System has been shown to be substantially equivalent to the currently marketed predicate devices.